

Nos. 14-1361, -1366
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE BRCA1- AND BRCA2- BASED HEREDITARY CANCER TEST
PATENT LITIGATION
UNIVERSITY OF UTAH RESEARCH FOUNDATION, THE TRUSTEES OF
THE UNIVERSITY OF PENNSYLVANIA, HSC RESEARCH AND
DEVELOPMENT LIMITED PARTNERSHIP, ENDORECHERCHE, INC., AND
MYRIAD GENETICS, INC.

Plaintiffs-Appellants,

v.

AMBRY GENETICS CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court for the Central District of Utah in
consolidated case no. 2:13-cv-00640, Judge Robert J. Shelby.

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

University of Utah v. Ambry Genetics Corporation

No. 14-1361; -1366

CERTIFICATE OF INTEREST

Counsel for the appellee, Ambry Genetics Corporation, certifies the following (use “None” if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Ambry Genetics Corporation

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Named Party, Ambry Genetics Corporation, is the real party in interest

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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September 29, 2014

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INTRODUCTION

The Supreme Court's decision in *Alice Corporation Party Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), confirms the district court's conclusion that a substantial question exists as to the patent eligibility of the claims remaining in this appeal.¹ Just as here, the patent-ineligible claims at issue in *Alice Corp.* were directed to an unpatentable abstract mental process and recited a generic physical embodiment to implement routine, conventional steps. The *Alice Corp.* opinion further contradicts the arguments Plaintiffs-Appellants ("Myriad") raise to argue for the patent-eligibility of their two method claims as well as their composition claims. Thus, Myriad's claims should suffer the same fate as Alice Corporation's.

ARGUMENT

A. The Physical Steps Recited in Method Claims 7 and 8 of the '441 Patent Do Not By Themselves Render Those Claims Patentable

Myriad contends that the district court erred when it likened claims 7 and 8 of the '441 patent to claim 1 of the same patent, the latter of which this Court in *Ass'n for Molecular Pathology v. USPTO* ("AMP II") found claimed an unpatentable abstract mental comparison. (Myriad Br. (ECF No. 33) at 28-32); 689 F.3d 1303, 1333-37 (Fed. Cir. 2012). In Myriad's view, claims 7 and 8, which depend from claim 1, are patentable just because they recite generic physical

¹ Myriad has withdrawn its appeal as to the '155 patent's method claims. The only method claims remaining for purposes of this litigation are the two method claims of the '441 patent. That patent expires—and thereby moots this litigation as to those method claims—on January 20, 2015.

limitations. (ECF No. 33 at 31-32 (“Here, in contrast [to claim 1], claims 7 and 8...unquestionably *apply* the abstract step of comparing the nucleotide sequences by requiring physical limitations” such as “hybridizing,” “detecting,” “amplifying,” and “sequencing....”) (emphasis in original).)²

Myriad’s argument echoes an argument Alice Corporation advanced that the Supreme Court soundly rejected. The claims at issue in *Alice Corp.* were drawn to the abstract idea of intermediated settlements and recited additional steps performed by a generic computer. 134 S. Ct. at 2358-59. Alice Corporation argued that the fact that the claimed generic computer “necessarily exist[s] in the physical, rather than purely conceptual, realm” rendered its claims patent eligible. *Id.*

In addition to being “beside the point,” the Supreme Court discarded this argument because to accept it would “eviscerat[e] the rule that ‘[l]aws of nature, natural phenomena, and abstract ideas are not patentable.’” *Id.* at 2359 (quoting *Ass’n for Molecular Pathology v. Myriad*, 133 S. Ct. 2107, 2116 (2013) (“*AMP III*”)). Accepting Alice Corporation’s argument would mean “an applicant could

² The district court’s factual findings include findings that these are conventional, routine, and generic steps. By not challenging these findings of fact, Myriad has not provided the Court with any basis to disturb them as clearly erroneous. *See Raytheon Co. v. U.S.*, 747 F.3d 1341, 1348 (Fed. Cir. 2014). Thus, the Court may reverse the district court’s conclusion that a substantial question of patent eligibility exists only if the district court abused its discretion by misapplying the law. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1147 (Fed. Cir. 2011). *Alice Corp.* confirms that no such abuse of discretion occurred here.

claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept.” *Id.* The Supreme Court explained that the combination of unpatentable subject matter and a generic physical application is no more patent eligible than a claim reciting only the unpatentable subject matter. *See id.* at 2358 (“[S]tating an abstract idea while adding the words apply it with a computer simply combines those two steps, with the same deficient results.”).

Alice Corp. confirms that the district court properly concluded that claims 7 and 8 are no more patent eligible than the abstract mental comparison of claim 1 this Court invalidated in *AMP II*. Myriad has merely claimed an abstract mental comparison with instructions to apply it through generic molecular biology techniques. The district court’s factual findings show that claim 7 adds to the unpatentable claim 1 only generic “gene probes” used in generic “hybridization” experiments, and claim 8 adds only generic “amplifying” and “sequencing” steps. (A88-100.) Such broad, generic, physical implementations add “nothing of substance to the underlying abstract idea.” *See Alice Corp.*, 134 S. Ct. at 2360.³

³ Myriad’s Reply Brief relies heavily on (1) Judge Bryson’s passing comment that Myriad was in an “excellent position to claim applications of that knowledge [of the BRCA gene],” citing ’441 patent, claim 21, not at issue here, and (2) the Supreme Court’s passing quotation of Judge Bryson’s *dicta*. *AMP II*, 689 F.3d at 1349; *AMP III*, 133 S. Ct at 2120. Judge Bryson never purported to assess whether Myriad’s ’441 patent claim 21 satisfied the inventive concept required by *Mayo* and *Alice Corp.* And as the District Court record confirms, Myriad did not patent

B. *Alice Corp.* Confirms that the District Court Correctly Analyzed the Additional Elements of the Method Claims Separate from the Unpatentable Subject Matter

Myriad complains that the district court ran afoul of *Diehr* and *Mayo* when the court “carv[ed] the claims into pieces – the natural law on one side and the remaining steps on the other – and evaluate[d] the remaining steps wholly apart from the natural law to determine if they are ‘conventional’ or ‘routine.’” (*E.g.*, Myriad Br. (ECF No. 33) at 32-36.) According to Myriad, “[t]he district court did here exactly what the Supreme Court in *Diehr* said was wrong - ignored the BRCA DNA sequences and simply looked to the other steps in the claims in the abstract to determine if they are ‘routine’ or ‘conventional.’ *Mayo* does not instruct the court to do this type of analysis.” (*Id.* at 33.)

To the contrary, *Alice Corp.* confirms that *Mayo* requires courts conducting § 101 patentability analysis to do *exactly* what the district court did here. Courts must evaluate the additional claim elements that purport to provide the “inventive concept” separate from the unpatentable subject matter according to “*Mayo*’s framework.” *Alice Corp.*, 134 S. Ct. at 2350. After determining that claims are directed to patent-ineligible concepts, courts must then “consider the elements of each claim both individually and ‘as an ordered combination’ to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible

“new” applications of the *BRCA* gene that satisfy the inventive concept requirement. *AMP III*, 133 S. Ct. at 2120.

application.” *Id.* at 2355-57 (citing, *inter alia*, *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S. Ct. 1289, 1297-98 (2012)).

The *Alice Corp.* Court explained the additional elements of the claims did not transform the unpatentable abstract idea into a patentable application. “Taking the claim elements separately, the function performed by the computer at each step of the process is ‘[p]urely conventional.’” *Id.* at 2359 (quoting *Mayo*, 132 S. Ct. at 1298). And when considered as an ordered combination, the computer components “ad[d] nothing ... that is not already present when the steps are considered separately.” *Id.* (quoting *Mayo*, 132 S. Ct. at 1298).

Here, the district court did exactly what *Alice Corp.* requires: The district court thoroughly examined the additional method claim elements, individually and as an ordered combination, and found on the undisputed record that they did not contain an inventive concept. (A88-100.)

In an argument related to its “inappropriate carving” argument, Myriad contends its method claims are patent eligible because the claimed patent-ineligible *BRCA* sequences were unknown until Myriad was the first to sequence and apply them. Myriad argues, for example:

[C]laims 7 and 8 set forth a new method of processing a patient sample to diagnose cancer risk through the use of the new probes and primers and a new gene sequence. Before Myriad’s discovery of the *BRCA1* gene, it would have been impossible to employ the claimed hybridizing, sequencing, and detecting steps because each of those steps depends on the knowledge of the *BRCA1* sequence.

(ECF No. 33 at 35.) But as *Mayo* makes clear, patent eligibility does not turn on whether the abstract idea, law of nature, or natural phenomena was previously unknown and whether some human activity was involved in creating its application. 132 S. Ct. at 1304.

In an analogous inquiry, the *Alice Corp.* Court soundly rejected an argument similar to Myriad's that divided abstract ideas into two categories: unpatentable, "preexisting fundamental truths that exist in principle apart from any human action" and patentable ideas that stem from human action. 134 S. Ct. at 2356 (alterations and internal quotations omitted). Alice Corporation argued that the idea of an intermediated settlement was patentable because a human conceived it. *Id.* The Court disagreed and stated that an abstract idea is *per se* patent ineligible if the idea is "fundamental" regardless of whether any "human action" created it, and claims reciting a fundamental idea and generic steps are not patent eligible. *Id.*

Myriad advocates for patent eligibility because it claims to have discovered the natural sequence of the *BRCA* gene and the first human action of accessing the sequence comparison through conventional, ubiquitous techniques. *Alice Corp.* and *Mayo* (and other precedents) preclude this distinction and any conclusion that the human action of sequencing, hybridizing or amplifying *BRCA* DNA by itself renders the claimed mental comparison patent eligible. Human action alone cannot transform unpatentable subject matter into patentable subject matter, and the Court

in *Alice Corp.* reiterated that combining generic methods with unpatentable subject matter does not render a claim patent eligible.

C. *Alice Corp.* Confirms that Myriad’s Method Claims Unlawfully Preempt

Alice Corp. further confirms that even a purportedly narrow method claim can improperly monopolize an abstract idea. The Court surveyed its decisions to reiterate the long-standing principle that to be patent eligible, the additional elements of the claim directed to unpatentable subject matter must improve the recited technology. *Id.* at 2357-58 (discussing *Benson*, *Flook*, *Mayo*, and *Diehr*). To this end, the Court found it dispositive that Alice Corporation neither “purport[ed] to improve the functioning of the computer itself” nor “effect[ed] an improvement in any other technology or technical field.” 134 S. Ct. at 2359-60 (citing *Mayo*, 132 S. Ct. at 1298; *Diamond v. Diehr*, 450 U.S. 175, 178-79 (1981)). Alice Corporation’s computer claims, while not the only way to apply the abstract idea, unlawfully preempted the abstract idea. *Id.*

So too do Myriad’s method claims. As the district court’s unchallenged findings of facts show, Myriad’s method claims recite ubiquitous methods of “amplification,” “sequencing,” and “hybridization” that insure a monopoly to the patent ineligible *BRCA1* sequence comparison. (A88-100.) “Given the ubiquity of [amplification, sequencing, and hybridization], wholly generic [] implementation[s are] not generally the sort of ‘additional feature[s]’ that provide[] ‘any practical

assurance that the process is more than a drafting effort designed to monopolize the [abstract mental comparison] itself.” *See Alice Corp.*, 134 S. Ct. at 2358. *Alice Corp.* confirms that the claims here effectively preempt the patent ineligible *BRCA1* sequence comparison.

D. *Alice Corp.* Confirms the District Court’s Finding of a Substantial Question of Patentability of Myriad’s Composition Claims

Applying the *Mayo* framework, the *Alice Corp.* Court also struck down the computer system claims at issue because “the system claims recite a handful of generic computer components configured to implement the same [patent-ineligible] idea.” 134 S. Ct. at 2360. In addition to being patent-ineligible products of nature under *AMP III*, *Chakrabarty*, and *Funk Brothers*, Myriad’s composition claims are further unpatentable under *Alice Corp.* because they are a generic component (natural *BRCA* sequence) used to amplify a person’s gene sequence to access the sequence information for the patent ineligible sequence comparison. The district court found the recited step of DNA amplification to be generic to obtaining the sequence, and a generic component (*e.g.*, a pair of DNA primers) is likewise unpatentable according to this line of reasoning from *Alice Corp.*

E. This Court's Applications of *Alice Corp.* Confirm the Soundness of the District Court's Reasoning

In *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, this Court affirmed summary judgment of patent ineligibility of method claims drawn to abstract ideas. 758 F.3d 1344 (Fed. Cir. 2014). The panel examined the additional elements of the claims separate from the abstract idea. *Id.* at 1350. The panel also found that human action by itself is not enough to confer patentability where the human action merely generates new information that is processed by a generic implementation: “[w]ithout additional limitations, a process that employs mathematical algorithms [created by human action] to manipulate existing information to generate additional information is not patent eligible.” *Id.* at 1351.

In *Buysafe, Inc. v. Google, Inc.*, this Court followed *Alice Corp.* and the *Mayo* framework to find unpatentable claims directed to an abstract idea and a generic computer. --- F.3d ---, 2014 WL 4337771, at *3-5 (Fed. Cir. Sept. 3, 2014). Among other reasons, the *Buysafe* panel determined that the additional claim elements, when analyzed separately from the abstract idea, did not add any “inventive concepts” to the claims. *Id.* at *4.

In *Planet Bingo, LLC v. VKGS LLC*, the Court applied *Alice Corp.* and found unpatentable claims reciting a generic computer implementation of the mental comparison of bingo numbers. --- Fed. Appx. ---, 2014 WL 4195188, at *3 (Fed. Cir. Aug. 26, 2014).

In *I/P Engine, Inc. v. AOL Inc.*, Judge Mayer filed a concurring opinion discussing *Alice Corp.* at length. --- Fed. Appx. ---, 2014 WL 3973501, at *9-12 (Fed. Cir. Aug. 15, 2014). Judge Mayer declared that a claim drawn to an abstract idea must also claim a “significant and well-defined” advance in science or technology. *Id.* at *9-10. I/P Engine failed to do so there, as Myriad has failed to do here. Additionally, in *I/P Engine*, the claimed technology (search engines), like the molecular biology methods here, were “well-established,” and the advantages of using those methods were “clear.” *Id.* at *11.

Sitting as a district judge, Judge Bryson applied *Alice Corp.* to find claims patent ineligible. *Loyalty Conversion Sys. Corp. v. Am. Airlines, Inc.*, Case No. 2:13-CV-00655, ECF No. 129 (E.D. Tex., Sept. 3, 2014). Judge Bryson concluded that: a generic computer cannot confer patent eligibility to claims directed to abstract ideas, *id.* at 16-18; additional elements considered separate from the abstract idea did not provide any inventive concepts, *id.* at 18-21; and limiting a claim to a particular technological environment (customer loyalty programs) still unlawfully preempted. *Id.* at 22-23.

CONCLUSION

For all the foregoing reasons, *Alice Corp.* confirms that the district court correctly concluded that a substantial question of patent eligibility exists as to all of Myriad’s asserted claims.

September 29, 2014 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed **DEFENDANT-APPELLEE'S SUPPLEMENTAL BRIEF** with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on September 29, 2014.

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